

DEC 21 2001

**510(k) Summary of Safety & Effectiveness**

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<b>Submitter</b>	Vanguard Medical Concepts, Inc. 5307 Great Oak Drive Lakeland, FL 33815
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<b>Contact</b>	Mr. Mike Sammon, Ph.D. Director, Research and Development (863) 683-8680, extension 228 (801) 327-3339 (facsimile) mikes@safe-reuse.com
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<b>Date</b>	June 14, 2001
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<b>Device</b>	<ul style="list-style-type: none"><li>• Trade Names: Vanguard Reprocessed Femoral Compression Device ⇒ USCI® C. R. Bard®, Inc., RADI Medical Systems AB FemoStop® Femoral Compression System</li><li>• Common Name: Femoral compression device, groin compressor</li><li>• Classification: 21 CFR 870.4450 – Vascular Clamp – Class II</li><li>• Product Code DXC</li></ul>
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<b>Predicate Device</b>	USCI® C. R. Bard®, Inc., RADI Medical Systems AB FemoStop® Femoral Compression System legally marketed under 510(k) premarket notification <u>K983471</u>
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<b>Indications for Use</b>	The femoral compression system is indicated for the compression of the femoral artery or vein following catheterization.
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<b>Contra-indications</b>	Femoral compression presents a significant risk for deep vein thrombosis in patients with severe peripheral vascular disease. Femoral artery or vein grafts are also at significant risk for damage with use of this device.
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## 510(k) Summary of Safety & Effectiveness, Continued

<b>Device Description</b>	<p>The femoral compression device is used to provide compression of the femoral artery for hemostasis management after catheterization. The device is comprised of an arch with an attached sterile pneumatic pressure dome, connector tube, stopcock and belt locks. A woven belt is used to secure the device onto the patient.</p> <p>In use, the belt is placed under and around the patient's hips and the arch is placed over the patient's groin with the dome atop the puncture site. The belt is attached to the arch via the adjustable belt locks and is tightened. A pneumatic pump and manometer are attached to the stopcock connector. The user controls the mechanical pressure applied to the puncture site by increasing or decreasing air pressure applied to the dome. The arch and belt absorb and distribute the opposing force from the dome.</p> <p>Vanguard receives previously used compression devices from healthcare facilities; cleans, inspects, tests, repackages and sterilizes the devices; and returns them to the healthcare facility.</p>
<b>Technological Characteristics</b>	<p>The Vanguard reprocessed compression device is essentially identical to the currently marketed OEM compression device. No changes are made to the currently marketed device's specifications and they possess the same technological characteristics. Biocompatibility and performance/functional testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.</p>
<b>Test Data</b>	<p>Decontamination and cleaning, sterilization validations and functional/performance and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective.</p>
<b>Conclusion</b>	<p>Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed femoral compression device is substantially equivalent to the predicate device, the OEM compression device, USCI® C. R. Bard®, Inc., RADI Medical Systems AB FemoStop® Femoral Compression System, under the Federal Food, Drug and Cosmetic Act.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 21 2001

Mike Sammon, Ph.D  
Director of Research & Development  
Vanguard Medical Concepts, Inc.  
5307 Great Oak Drive  
Lakeland, FL 33815

Re: K011832

Trade Name: Vanguard Reprocessed Femoral Compression Device  
Regulation Number: 21 CFR 870.4550  
Regulation Name: Femoral Compression Device  
Regulatory Class: Class II (two)  
Product Code: DXC  
Dated: September 18, 2001  
Received: September 24, 2001

Dear Dr. Sammon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

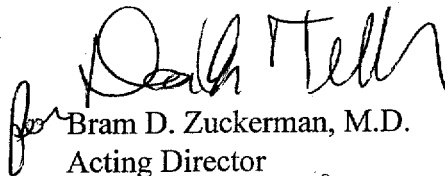
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
Bram D. Zuckerman, M.D.

Acting Director  
Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number:

Device Name: Vanguard Reprocessed Femoral Compression Device

Indications for Use:

The femoral compression system is indicated for the compression of the femoral artery or vein following catheterization.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K011832